Complete Summary

GUIDELINE TITLE

Consensus recommendations for managing patients with nonvariceal upper gastrointestinal bleeding.

BIBLIOGRAPHIC SOURCE(S)

Barkun A, Bardou M, Marshall JK. Consensus recommendations for managing patients with nonvariceal upper gastrointestinal bleeding. Ann Intern Med 2003 Nov 18;139(10):843-57. [192 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

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EVIDENCE SUPPORTING THE RECOMMENDATIONS

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QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Nonvariceal upper gastrointestinal bleeding

GUIDELINE CATEGORY

Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Critical Care
Emergency Medicine
Family Practice
Gastroenterology
Internal Medicine

Pharmacology Surgery

INTENDED USERS

Hospitals Pharmacists Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based clinical practice guidelines on acute management of patients with nonvariceal upper gastrointestinal bleeding

TARGET POPULATION

Patients with nonvariceal bleeding largely due to peptic ulcers

Note: The recommendations also apply to patients who have ulcers associated with nonsteroidal anti-inflammatory drugs. The roles of cyclooxygenase-2 selective inhibitors, co-prescription, or Helicobacter pylori eradication in patients with bleeding ulcers associated with nonsteroidal anti-inflammatory drugs were beyond the scope of the consensus conference, which focused principally on acute management.

INTERVENTIONS AND PRACTICES CONSIDERED

Refer to the "Major Recommendations" field for appropriate context.

Initial Management

- 1. Multidisciplinary management protocol
- 2. Training of endoscopy support staff
- 3. Immediate patient evaluation and resuscitation
- 4. Consider nasogastric tube placement

Risk Stratification/Evaluation

1. Clinical (nonendoscopic) stratification and early endoscopic stratification using prognostic scales

Endoscopic Therapy

- 1. Early endoscopy
 - Targeted irrigation for clot dislodgement as needed
- 2. Endoscopic hemostatic therapy
 - Endoscopic injection therapy
 - Thermal coaptive therapy
 - Monotherapy or combination therapy
 - Endoscopic clips
- 3. Second attempt for rebleeding
- 4. Surgical consultation

Pharmacotherapy

- 1. H₂-receptor antagonists (not recommended)
- 2. Somatostatin and octreotide (not recommended routinely)
- 3. Intravenous bolus and infusion proton-pump inhibitor
- 4. Feeding following endoscopy for low-risk patients
- 5. Non-urgent testing for Helicobacter pylori and eradication

MAJOR OUTCOMES CONSIDERED

- Morbidity and mortality associated with bleeding
- Effectiveness of treatment/management based on:
 - Rebleeding
 - Rates of surgery and surgical complications
 - Mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases Searches of Patient Registry Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature review methods for relevant articles included MEDLINE searches and manual searches of bibliographies of key articles published in English between 1966 and June 2002. Search terms included upper GI bleeding, non-variceal, guidelines, meta-analysis, naso-gastric tube, risk stratification, re-bleeding, mortality, surgery, endoscopy, second-look, clot, stigmata, injection, thermal coaptive, laser, hemostatic clips, proton pump inhibitor, histamine receptor antagonist, somatostatin, and octreotide. The working group referred to past reviews, meta-analyses, and published consensus conferences to summarize data up to 1992.

NUMBER OF SOURCE DOCUMENTS

More than 875 articles were initially reviewed.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The classification system of the Canadian Task Force on the Periodic Health Examination to assess therapeutic literature was used.

Quality of evidence

- I Evidence obtained from at least 1 properly randomized, controlled trial
- II-1 Evidence obtained from well-designed controlled trials without randomization
- II-2 Evidence obtained from well-designed cohort or case—control analytic studies, preferably from more than 1 center or research group
- II-3 Evidence obtained from comparisons between times or places with or without the intervention, or dramatic results in uncontrolled experiments
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Analysis

New systematic reviews were conducted on data from the past 10 years on the prevalence and natural history of nonvariceal gastrointestinal bleeding, risk stratification, and various management strategies. Data were formally reviewed, including previous consensus opinions (for recommendations 1, 2, 3, and 18), narrative reviews (for recommendations 4, 11, 12, 13, 14, and 19), systematic reviews (for recommendations 5.1, 5.2, 6, and 20), and meta-analyses (for recommendations 7, 8, 9, 10, 15, 16, and 17).

Data available only in abstract form were not considered, with the exception of results from 2 meta-analyses by Bardou and colleagues from McGill University and the Canadian Registry in Upper Gastrointestinal Bleeding and Endoscopy (RUGBE) initiative, which had been submitted for publication at the time of writing of this manuscript. In addition, for recommendations 7 and 10, data from pivotal abstracts were discussed in detail and were published within 3 months following the conference. Consequently, a post-conference Delphi process was carried out and results from this final vote were included.

A series of original meta-analyses, including 71 articles and nearly 9,000 patients, were performed.

Economic considerations were recognized, but the country-specific nature of most cost data limited the review.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference) Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The recommendation statements were developed according to generally accepted standards. A 7-step approach addressing most of 37 pertinent criteria of validity was followed.

Delphi Consensus Process

A Delphi consensus process was initiated 6 weeks before the consensus conference to circulate preliminary statements and evidence. Each statement was graded to indicate the level of evidence available and the strength of the recommendation by using the classification system of the Canadian Task Force on the Periodic Health Examination. This scheme was developed to assess therapeutic literature, not literature addressing prognosis.

Consensus Conference

A 2-day consensus conference was held in June 2002 under the auspices of the Canadian Association of Gastroenterology. The conference was conducted according to generally accepted standards for the development of clinical practice guidelines. At the consensus conference, data were presented and the statements and the grades attributed to evidence were discussed, modified if necessary, and voted on by each participant according to recognized criteria, as follows:

The voting schema

- a. Accept completely
- b. Accept with some reservation
- c. Accept with major reservation
- d. Reject with reservation
- e. Reject completely

Note: Statements for which more than 50% of participants voted a, b, or c were accepted.

Preparation Process and Format of the Report

A working group drafted the manuscript, which was then reviewed by all voting conference participants and the nonvoting chair.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of recommendations

A There is good evidence to support the procedure or treatment.

B There is fair evidence to support the procedure or treatment.

C There is poor evidence to support the procedure or treatment, but recommendations may be made on other grounds.

D There is fair evidence that the procedure or treatment should not be used.

E There is good evidence that the procedure or treatment should not be used.

COST ANALYSIS

Selected cost analyses were reviewed as follows:

Early Endoscopy

In patients at low risk, 2 randomized, controlled trials have demonstrated cost reductions of 43 to 91% with the use of early endoscopy.

Proton-pump inhibitors

Recent analyses suggest that pre-endoscopy administration of proton-pump inhibitors may be cost-effective in certain situations.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The drafted manuscript was circulated for review by voting conference participants and the nonvoting chair, who approved the final draft.

A post-conference Delphi process was carried out, and results from 2 newly published articles that had initially been included as abstracts were reviewed and included in the draft.

A representative from the Canadian Association of General Surgeons reviewed the consensus guidelines a posteriori.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the Quality of Evidence (I, II-1, II-2, II-3, and III), the Classification of Recommendations (A, B, C, D, and E), and the Voting Schema (a, b, c, d, e) are provided at the end of the "Major Recommendations" field.

Initial Management

Recommendation 1: Hospitals should develop institution-specific protocols for multidisciplinary management, which should include access to an endoscopist with training in endoscopic hemostasis. Recommendation: C (vote: a, 100%); Evidence: III

Recommendation 2: Support staff trained to assist in endoscopy should be available for urgent endoscopy. Recommendation: C (vote: a, 92%; b, 8%); Evidence: III

Recommendation 3: Immediate evaluation and appropriate resuscitation are critical to proper management. Recommendation: C (vote: a, 96%; b, 4%); Evidence: III

Recommendation 4: In selected patients, the placement of a nasogastric tube can be considered because the findings may have prognostic value.

Recommendation: B (vote: a, 40%; b, 36%; c, 24%); Evidence: II-3

Risk Stratification

Recommendation 5.1: Clinical (nonendoscopic) stratification of patients into low- and high-risk categories for rebleeding and mortality is important for proper management. Available prognostic scales may be used to assist in decision-making. Recommendation: B (vote: a, 76%; b, 24%); Evidence: II-2

Recommendation 5.2: Early stratification of patients into low- and high-risk categories for rebleeding and mortality, based on clinical and endoscopic criteria, is important for proper management. Available prognostic scales may be used to assist in decision making. Recommendation: A (vote: a, 96%; b, 4%); Evidence: I

Endoscopic Therapy

Recommendation 6: Early endoscopy (within the first 24 hours) with risk classification by clinical and endoscopic criteria allows for safe and prompt discharge of patients classified as low risk (Recommendation: A [vote: a, 92%; b, 8%]; Evidence: I); improves patient outcomes for patients classified as high risk (Recommendation: C [vote: a, 64%; b, 36%]; Evidence: II-2); and reduces resource utilization of patients classified as either low or high risk (Recommendation: A [vote: a, 88%; b, 12%]; Evidence: I).

Recommendation 7: A finding of low-risk endoscopic stigmata (a clean-based ulcer or a nonprotuberant pigmented dot in an ulcer bed) is not an indication for endoscopic hemostatic therapy (Recommendation: A [vote: a, 100%]; Evidence: I). A finding of a clot in an ulcer bed warrants targeted irrigation in an attempt at dislodgment, with appropriate treatment of the underlying lesion (Recommendation: A [vote: a, 72%; b, 28%]; Evidence: I). A finding of high-risk endoscopic stigmata (active bleeding or a visible vessel in an ulcer bed) is an indication for immediate endoscopic hemostatic therapy (Recommendation: A [vote: a, 100%]; Evidence: I).

Recommendation 8: No single solution for endoscopic injection therapy is superior to another for hemostasis. Recommendation: A (vote: a, 92%; b, 8%); Evidence: I

Recommendation 9: No single method of endoscopic thermal coaptive therapy is superior to another. Recommendation: A (vote: a, 100%); Evidence: I

Recommendation 10: Monotherapy, with injection or thermal coagulation, is an effective endoscopic hemostatic technique for high-risk stigmata; however, the combination is superior to either treatment alone. Recommendation: B (vote: a, 48%; b, 48%; c, 4%); Evidence: I

Recommendation 11: The placement of clips is a promising endoscopic hemostatic therapy for high-risk stigmata. Recommendation: B (vote: a, 44%; b, 52%; c, 4%); Evidence: I

Recommendation 12: Routine second-look endoscopy is not recommended. Recommendation: E (vote: a, 92%; b,8%); Evidence: I

Recommendation 13: In cases of rebleeding, a second attempt at endoscopic therapy is generally recommended. Recommendation: A (vote: a, 100%); Evidence: I

Recommendation 14: Surgical consultation should be sought for patients who have failed endoscopic therapy. Recommendation: B (vote: a, 100%); Evidence: II-2

Pharmacotherapy

Recommendation 15: H_2 -receptor antagonists are not recommended in the management of patients with acute upper gastrointestinal (GI) bleeding. Recommendation: D (vote: a, 92%; b, 8%); Evidence: I

Recommendation 16: Somatostatin and octreotide are not recommended in the routine management of patients with acute nonvariceal upper GI bleeding. Recommendation: C (vote: a, 96%; b, 4%); Evidence: I

Recommendation 17: An intravenous bolus followed by continuous-infusion proton-pump inhibitor is effective in decreasing rebleeding in patients who have undergone successful endoscopic therapy. Recommendation: A (vote: a, 100%); Evidence: I

Recommendation 18: In patients awaiting endoscopy, empirical therapy with a high-dose proton pump inhibitor should be considered. Recommendation: C (vote: a, 40%; b, 32%; c, 16%; d, 12%); Evidence: III

Recommendation 19: Patients considered at low risk for rebleeding after endoscopy can be fed within 24 hours. Recommendation: A (vote: a, 88%; b, 12%); Evidence: I

Recommendation 20: Patients with upper GI bleeding should be tested for Helicobacter pylori and receive eradication therapy if infection is present. Recommendation: A (vote: a, 96%; b, 4%); Evidence: I

Definitions

Quality of evidence

- I Evidence obtained from at least 1 properly randomized, controlled trial
- II-1 Evidence obtained from well-designed controlled trials without randomization
- II-2 Evidence obtained from well-designed cohort or case—control analytic studies, preferably from more than 1 center or research group
- II-3 Evidence obtained from comparisons between times or places with or without the intervention, or dramatic results in uncontrolled experiments
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Classification of recommendations

- A There is good evidence to support the procedure or treatment.
- B There is fair evidence to support the procedure or treatment.
- C There is poor evidence to support the procedure or treatment, but recommendations may be made on other grounds.
- D There is fair evidence that the procedure or treatment should not be used.
- E There is good evidence that the procedure or treatment should not be used.

Voting schema*

- a. Accept completely.
- b. Accept with some reservation.
- c. Accept with major reservation.
- d. Reject with reservation.
- e. Reject completely.

CLINICAL ALGORITHM(S)

None provided

 $^{^{\}star}$ Statements for which more than 50% of participants voted a, b, or c were accepted.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- · Reduced morbidity/mortality associated with bleeding
- Decreased recurrence of bleeding
- Reduced length of hospital stay
- Reduced need for surgery/transfusions
- Reduced costs

POTENTI AL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Recommendation 12: Second-look endoscopy may be of statistical benefit in select high-risk patients, but data are conflicting regarding its routine use.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Barkun A, Bardou M, Marshall JK. Consensus recommendations for managing patients with nonvariceal upper gastrointestinal bleeding. Ann Intern Med 2003 Nov 18;139(10):843-57. [192 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Nov 18

GUIDELINE DEVELOPER(S)

Canadian Association of Gastroenterology - Medical Specialty Society

SOURCE(S) OF FUNDING

The Canadian Association of Gastroenterology administered all aspects of the meeting and secured multipartner funding from industry sponsors. Additional funds were obtained through a peer-review grant received by the Canadian Institutes of Health Research and an internal award from the Research Institute of the McGill University Health Centre.

GUIDELINE COMMITTEE

Nonvariceal Upper Gastrointestinal Bleeding Consensus Conference Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Alan Barkun, MD, MSc; Marc Bardou, MD, PhD; John K. Marshall, MD, MSc

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Statements of conflicts of interest were obtained from all voting participants, and additional ethical information was collected.

Potential Financial Conflicts of Interest: Consultancies: A. Barkun (Altana Pharma Canada Inc.); Honoraria: A. Barkun (Altana Pharma Canada Inc.); Grants received: A. Barkun (Altana Pharma Canada Inc.).

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Annals of Internal Medicine Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from Alan Barkun, MD, MSc, Division of Gastroenterology, Montreal General Hospital Site, McGill University Health Centre, 1650 Cedar Avenue, Room D7.148, Montreal, Quebec H3G 1A4, Canada.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 5, 2004. The information was verified by the guideline developer on May 20, 2004.

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